60th Medical Group (AMC), Travis AFB, CA

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)

FINAL REPORT SUMMARY

(Please type all information. Use additional pages if necessary.)

PROTOCOL #: FDG20160026A   **DATE:** 4 May 2017

PROTOCOL TITLE: The Effect of Infrarenal Aortic Balloon Occlusion on Weaning from Supraceliac Aortic Balloon Occlusion in a Porcine Model (*Sus scrofa*) of Hemorrhagic Shock.

PRINCIPAL INVESTIGATOR (PI) / TRAINING COORDINATOR (TC): Capt Emily Tibbits

DEPARTMENT: SGSE   **PHONE #:** 937-901-6095

INITIAL APPROVAL DATE: 25 August 2016   **LAST TRIENNIAL REVISION DATE:** N/A

FUNDING SOURCE: SG

1. **RECORD OF ANIMAL USAGE:**

Animal Species:	Total # Approved	# Used this FY	Total # Used to Date
Sus scrofa	23	19	19

2. **PROTOCOL TYPE / CHARACTERISTICS:** (Check all applicable terms in **EACH** column)

___ Training: Live Animal	___ Medical Readiness	___ Prolonged Restraint
___ Training: non-Live Animal	___ Health Promotion	___ Multiple Survival Surgery
___ Research: Survival (chronic)	___ Prevention	___ Behavioral Study
_X_ Research: non-Survival (acute)	___ Utilization Mgt.	___ Adjuvant Use
___ Other ( )	___ Other (Treatment)	___ Biohazard

3. **PROTOCOL PAIN CATEGORY (USDA):** (Check applicable)   ___ C   _X_ D   ___ E

4. **PROTOCOL STATUS:**

    *Request Protocol Closure:

    ___ Inactive, protocol never initiated

    ___ Inactive, protocol initiated but has not/will not be completed

    _X_ Completed, all approved procedures/animal uses have been completed

5. **Previous Amendments:**
    List all amendments made to the protocol.. **IF none occurred, state NONE. Do not use N/A.**

    For the Entire Study Chronologically

Amendment Number	Date of Approval	Summary of the Change
1	19 Sept 16	Procedures, Anesthetic/Analgesic/Antibiotic, Biosample
2	28 Sept 16	Procedures, Anesthetic/Analgesic/Antibiotic, Biosample
3	9 Nov 16	Procedures, animal care, biosamples, protocol

4	15 Dec 16	Personnel
5	11 Jan 17	Animal Use, Procedures
6	20 Feb 17	Personnel
7	6 Mar 17	Procedures

6.   FUNDING STATUS: Funding allocated: $43,372   Funds remaining: $ 0

7.   PROTOCOL PERSONNEL CHANGES:

Have there been any personnel/staffing changes (PI/CI/AI/TC/Instructor) since the last IACUC approval of protocol, or annual review?   _X_ Yes   ___ No

If yes, complete the following sections (Additions/Deletions). For additions, indicate whether or not the IACUC has approved this addition.

ADDITIONS: (Include Name, Protocol function - PI/CI/AI/TC/Instructor, IACUC approval - Yes/No)

Maj Robert Faulconer (AI) Yes, Col Jeremy Cannon (AI), Yes, Mr. Steven Chu (AI) Yes

DELETIONS: (Include Name, Protocol function - PI/CI/AI/TC/Instructor, Effective date of deletion)

None

8.   PROBLEMS / ADVERSE EVENTS: Identify any problems or adverse events that have affected study progress. Itemize adverse events that have led to unanticipated animal illness, distress, injury, or death; and indicate whether or not these events were reported to the IACUC.

We had to exclude three animals from our study due to technical errors on the part of the investigators. These events were reported to the IACUC.

9.   REDUCTION, REFINEMENT, OR REPLACEMENT OF ANIMAL USE:

REPLACEMENT (ALTERNATIVES): Since the last IACUC approval, have alternatives to animal use become available that could be substituted in this protocol without adversely affecting study or training objectives?

No.

REFINEMENT: Since the last IACUC approval, have any study refinements been implemented to reduce the degree of pain or distress experienced by study animals, or have animals of lower phylogenetic status or sentience been identified as potential study/training models in this protocol?

No.

REDUCTION: Since the last IACUC approval, have any methods been identified to reduce the number of live animals used in this protocol?

No.

10.   PUBLICATIONS / PRESENTATIONS: (List any scientific publications and/or presentations that have resulted from this protocol. Include pending/scheduled publications or presentations).

The first or two abstracts for this protocol was submitted to Excelsior for presentation. The second is in progress and will be submitted for presentation at EAST. Both manuscripts are in progress and will be submitted for publication following presentation of the corresponding abstracts.

11.   Were the protocol objectives met, and how will the outcome or training benefit the DoD/USAF?

Yes, the protocol objectives were met. While data analysis is still underway, the results from this study will make a significant contribution to the REBOA literature and address important questions regarding applicability of REBOA in different positions for different therapeutic goals. This will, in turn, help to guide the practice of those providing resuscitative care to our critically injured service members.

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12. PROTOCOL OUTCOME SUMMARY: (Please provide, in "ABSTRACT" format, a summary of the protocol objectives, materials and methods, results - include tables/figures, and conclusions/applications.)

Objectives: One limitation of Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) is hemodynamic instability upon balloon deflation due to distal hyperemia and washout of ischemic metabolites. We sought to determine whether stepwise reperfusion after supraceliac (Zone-1) REBOA by transitioning to infrarenal (Zone-3) occlusion would mitigate the physiologic consequences of balloon deflation and decrease hemodynamic instability.

Methods: Twelve anesthetized swine underwent controlled hemorrhage of 25% blood volume, 45 minutes of Zone-1 REBOA, then resuscitation with shed blood. Standardized critical care began with deflation of the Zone-1 balloon in all animals, and continued for six hours. Half of the animals were randomly assigned to Zone-3 REBOA for an additional 45 minutes following Zone-1 balloon deflation.

Results: There were no differences in physiology at baseline, during the initial 30 minutes of hypotension, or during the 45 minutes of Zone-1 occlusion. After Zone-1 balloon deflation, there was no difference in proximal mean arterial pressure (pMAP) with or without Zone-3 occlusion, or percentage of critical care time spent within the target pMAP range between 65 and 75 mm Hg. There were also no significant differences in peak lactate concentration or resuscitation requirements.

Conclusions: In an animal model of hemorrhagic shock and Zone-1 REBOA, subsequent Zone-3 aortic occlusion did not add significant ischemic burden, but it also did not provide significant hemodynamic support. The effect of this strategy on functional outcomes warrants further study. Continued investigation is necessary to determine optimal resuscitative support strategies during reperfusion following Zone-1 REBOA.

X _____
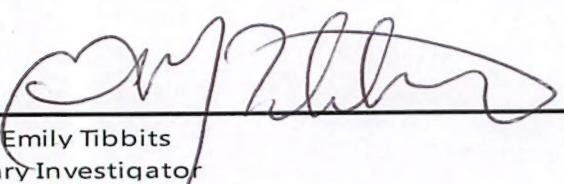
Capt Emily Tibbits
Primary Investigator

Attachments:
Attachment 1: Defense Technical Information Center (DTIC) Abstract Submission **(Mandatory)**

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This abstract requires a brief (no more than 200 words) factual summary of the most significant information in the following format: Objectives, Methods, Results, and Conclusion.

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Conclusion: In an animal model of hemorrhagic shock and Zone-1 REBOA, subsequent Zone-3 aortic occlusion did not add significant ischemic burden, but it also did not provide significant hemodynamic support. Continued investigation is necessary to determine optimal resuscitative support strategies during reperfusion following Zone-1 REBOA.

Grant Number:_____
From:_____
**If you utilized an external grant, please provide Grant # and where the grant came from. Thank you.

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